

Marked-up  
Specification

***DEVICE FOR ENHANCING WELL-BEING***

This is a 371 National Stage application of International application no. PCT/ZA2003/000170, filed November 12, 2003, which claims priority to South African application no. 2002/3851, filed November 15, 2002. The entire contents of the above-referenced applications are hereby incorporated by reference in their entirety.

***TECHNICAL FIELD OF THE INVENTION***

This invention relates to a device for enhancing the well-being of humans and any animals who can be made to use the device.

The term “well-being” is chosen to include the alleviation of disease and other physiological problems, as well as to improve performance in many aspects of life such as sport and other functions; and also to contribute to the regulation of the immune system.

In a particular application of the invention the treatment of asthma and emphasemia has been examined.

***BACKGROUND ART***

Research has been carried out on the absorption or adsorption of oxygen to the iron sites of the haemoglobin molecule. Thus, oxygen molecules cross the alveolar-capillary membrane and are dissolved in the plasma. The amount of dissolved oxygen in the

plasma is known to be important and it is the haemoglobin that is responsible for the amount of oxygen in the blood. Approximately 1.3 ml of oxygen dissolve in 1 gm of haemoglobin.

It is an object of the present invention to provide a device which maximises the entry of oxygen into the plasma and attachment or oxygen onto the haemoglobin cells to form oxy- haemoglobin.

#### **DISCLOSURE SUMMARY OF THE INVENTION**

According to the invention a device is provided which includes an inlet for oxygen or air and an outlet, preferably in the form of a mouthpiece, and a means for providing an electromagnetic field such as a magnetic field between the inlet and the outlet, the magnetic field being sufficient to induce paramagnetism to the oxygen.

#### **BRIEF DESCRIPTION OF THE DRAWING**

An example of the invention is illustrated in the accompanying drawing which is cross-section of a device according to the invention. The device includes an inlet (10) for air, a body (12) including a permanent magnet (11) of strength above 1500 gauss and a mouthpiece (13). With the mouthpiece in position, the patient draws air through the body and past the magnet, thereby inducing paramagnetism in the oxygen.

**DETAILED DESCRIPTION OF THE INVENTION**

In a preferred form of the invention the magnetic field is created by a permanent magnet, electromagnet or other source of magnetic field in the device, and the strength of the magnetic field is preferably but not limited to the order of 1,500 gauss to 3,000 gauss.

The arrangement of inlet and mouthpiece is designed for the person using the device to draw air through the device but it will be appreciated that means may be provided to assist the passage of the oxygen-containing gas through the device. This may be particularly useful in anaesthesiology by providing the patient with increased oxygen supply during anaesthetic procedures.

Experiments have shown that use of the device leads to a definite improvement to the immune system and there have also been exciting improvements in the enhancement of performance and well-being.

A number of surveys were conducted to support the effectivity of the invention.

**Survey 1**

Fourteen athletes were selected for the survey. Ten were supplied with a device (called THERAHALER,( i.e. an inhaler device)) according to the invention and four were not.

The results are given in the following table.

**TABLE**

TEST PARAMETER	ATHLETES USING THERAHALER (10)				ATHLETES USING PLACEBO (4)		
	AT START	AFTER 4 WEEKS	CHANGE		AT START	AFTER 4 WEEKS	CHANGE
RESTING HEART RATE (BEATS PER MINUTE AVERAGE)	66,14	61,8	-7,35%		64,75	66,5	+1,02%
HEART RATE AFTER 15 MINUTES EXERCISE ROUTINE (BEATS PER MINUTE AVERAGE ATHLETE)	160,2	150,5	-6,0%		163,75	165,00	-0,91%
AFTER 1 MINUTE REST (BEATS PER MINUTE) AVERAGE PER ATHLETE	122,7	105,6	-13,9%		123,00	124,25	+1,0%
AFTER 3 MINUTES REST (BEATS PER MINUTE) AVERAGE PER ATHLETE	91,3	81,1	-11,7%		92,25	98,25	+6,5%
BREATH HOLDING TIME (SECONDS)				BREATH HOLDING TIME (SECONDS)			
AVERAGE PER ATHLETE	67,3	73,2	+26,9		54,5	57,25	+5%

**COMMENTS:**

1. Test subjects: 14 above average athletes, volunteers from various athletic disciplines. 10 used **THERAHALER** every 30 minutes for 4 weeks, 4 used **placebos**.
2. Test subject's fitness / endurance capabilities were tested
  - a) at commencement
  - b) after 4 weeks

using an exercise bicycle with variable, measurable loading as per chart and heart rate per minute was measured at intervals indicated. All subjects continued with normal training regime during the test period. (4 weeks)
3. The athletes were required to use their device thus:
  - a) Expel air from lungs.

- b) Inhale atmospheric air through the THERAHALER / PLACEBO until lungs were full.
- c) Hold breath as long as possible (measured in seconds)
- d) Exhale
- e) Repeat every 30 minutes during waking hours

### Survey 2

This survey was conducted on 28 top class rugby players - 20 without THERAHALER and 8 using THERAHALER every 30 minutes.

The test used was the 20 m “Bleep Test” where a player is required to run 20 m between beacons, each lap a little faster than the last. When a participant cannot keep up the pace set by a bleep, he is disqualified.

The 28 players performed a total of 2643 laps (average 104 - 26 laps per player).

### Report ONE

Three weeks synopsis of 12 Players:

Without THERAHLER (7 Players)	With THERAHALERS (5 Players)
Extra number of laps completed...100	Extra number of laps completed...128
Average Extra per Player...14.29	Average Extra per Player...25.6
Improvement as % of base (104.26)...13.7%	Improvement as % of base...24.44%

### Report TWO

Synopsis of Performance Improvement of all 24 Players over 1 to 4 weeks:

Without THERAHLER (16 Players)	With THERAHALERS (8 Players)
Total 38 Weeks Usage	Total 22 Weeks Usage
255 Extra laps	196 Extra Laps
Improved Laps per week...6.7	Improved Laps per week...8.9

(2.2 Extra over Non THERAHALER Players) = 2% Improvement in Performance

**OBSERVATIONS:**

1. Players who use THERAHALER can expect to attain an extra 25% improvement in fitness levels after three weeks over player who do not use THERAHALER.
2. The greater percentage of THERAHALER players completing the three week course, held during a flu epidemic, would substantiate improve immune system function observed with the ASTHMATIC patient trial.
3. Players using THERAHALER reported an improved feeling of WELL BEING (as did ASTHMA patients) which indicates an improved confidence level and an improved all round state of health.
4. Tests using work load bicycle and measuring heart work & recovery rates yield supportive results, but in this rest, 25% placebos were used and they showed disappointing results –

**SURVEY 3**

A quality of life study was completed by 45 asthmatic patients as required by protocol for Juniper Quality of Life Questionnaires (AQLQ).

The protocol was constructed as follows:

- a. 14 day observation period to ascertain the stability of the patients condition.
- b. 28 day intensive ~~Therahaler~~ THERAHALER therapy (every 30 mins).
- c. Second 28 day intensive ~~Therahaler~~ THERAHALER Therapy.

- d. 30 day maintenance Therahaler THERAHALER Therapy (6 x per day to establish whether the benefits gained in the 56 day intensive therapy period were lasting or not.
- e. Final patient check up - it is at this period that these patient feedback reports are filled in.

## End of Study Patient Feedback Report

(45 Patients)

1. What is your overall view on the <u>Therahaler THERHALER</u> ?		
Positive : 81%	Negative : 2%	Indifferent : 17%

2. Would you recommend the use of <u>Therahaler TERAHALER</u> to other people with Asthma?		
Yes : 76%	No : 2%	Maybe : 22%

3. Name three ways in which <u>Therahaler TERAHALER</u> has changed your life :	
BETTER BREATHING : 67%	MORE CONFIDENCE : 58%
MORE ACTIVE : 67%	LESS DURGS : 71%
BETTER SLEEPING : 69%	NO COUGH : 69%

4. If there were any changes to be made to the <u>Therahaler TERAHALER</u> – What would they be?		

5. Have you noticed an improvement in your Asthma since using the <u>Therahaler TERAHALER</u> ?		
Yes 62%	No 9%	Not Sure 29%

If you answered "Yes" on a scale of 1-10, (1 being the least and 10 being the most) how much improvement have you noted?

Not Sure: 11%	0 = 7%	1 = 0%
2 = 6%	3 = 7%	4 = 7%
5 = 4%	6 = 16%	7 = 9%
8 = 16%	9 = 4%	10 = 13%

6. With regard to night time sleep since using the <u>Therahaler TERAHALER</u> ?		
a) Your sleep pattern is better : 69%	b) I have more disturbed nights : ~	c) There is no change : 31%

7. With regard to exercise and physical ability?		
a) I am stronger : 67%	b) I tire quicker : ~	c) There is no change : 33%

8. Since using the <u>Therahaler TERAHALER</u> I use my reliever inhaler?		
a) Less : 71%	b) More : ~	c) The same amount : 29%

9. The use of the <u>Therahaler TERAHALER</u> has resulted in :		
a) Less Cough : 69%	b) More Cough : ~	c) No Change in Cough : 31%

10. Do you intend to continue using <u>Therahaler TERAHALER</u> :		
a) Yes : 76%	b) No : 9%	c) Undecided : 15%

11. SUMMARY :		

The results of the response to the questions for the first and last visits of patients were analyzed to investigate whether there was any significant improvement in the quality of life as measured by the questions of the AQLQ(S) questionnaire.

A paired t-test was applied to each of the 32 questions. For most of the questions, the sample size was n=44 except in a few cases where a patient may not have answered a particular question. All the questions, with the exception of question 12, showed a significant improvement. This is shown by the negative values of the t-statistic with accompanying p-values < 0.01 for all questions but for question 4 which had a p-value=0.03<0.05 (The difference for the paired t-statistic was taken as d = score on visit 1 – score on visit 5. A negative difference is an indication of an improvement).

Question 12 which asks “How much discomfort have you felt over the past 2 weeks as a result of coughing?” yielded  $t=-1.375$  with a p-value of 0.176 and although not significant at a 5% level of significance, still indicates an improvement.

The statistical results thus show that the use of the Therahaler THERAHALER has improved the patients’ quality of life as measured by the AQLQ(S) questionnaire.

In Addition:

- 1 All patients report being able to breathe easier and can better perform their normal functions at work and home and enjoy a improved quality of life.

2 All patients had experienced frequent Asthma attacks – some near fatal before using THERAHALER since completing their eight week regimine.

3 With one exception, all patients have significantly reduced their medicine intake – two have stopped carrying their Bronchial dilator pumps around with them, and some have stopped using cortico steroids.

4 Three patients got flu and one bronchitis after completing the test and reported no deterioration in their asthma, indicating that their immune system was functioning normally.

5 Many patients can now enjoy foods, which they could not previously enjoy because it would trigger an asthma attack, again indicating that their immune systems have improved.

6 No adverse reactions or experiences were felt and all patients reported that they preferred using the THERAHALER because it is a non-medicated option utilizing natural principles.

7 Improvement in peak flow meter readings indicated an improvement in lung function.

8 Patients reported enjoying an uninterrupted nights sleep completing the THERAHALER regime, because wheezing and coughing had diminished or had ceased altogether.

#### SURVEY 4

This survey was aimed to determine the effects of regular use of THERAHALER on arterial blood gas concentrations and T Cell numbers.

**METHOD**

1. 7 THERAHALER board members were recruited for the study.
2. Blood sampling involved taking an arterial blood sample from the radial artery and a venous sample from the brachial vein for T Cell analysis.
3. The arterial blood sample was analysed for the following parameters:
  - i) Partial pressure of oxygen (PO<sub>2</sub>)
  - ii) Partial pressure of carbon dioxide (PCO<sub>2</sub>)
  - iii) Oxy-haemoglobin percentage (O<sub>2</sub>Hb)
  - iv) Carboxyhaemoglobin percentage (COHb)
  - v) Methaemaglobin percentage (metHb)
  - vi) Haemoglobin concentration (Hb)
4. The venous blood sample was analysed and the following counts were conducted:
  - i) CD3 Count
  - ii) CD4 Count
  - iii) CD8 Count
5. Baseline sampling (arterial and venous) was done on all subjects.
6. The test subjects were then instructed to use the THERAHALER every 5 minutes for the next two hours and repeat arterial sampling was conducted.
7. The subjects were then sent home and requested to use the THERAHALER as directed every 30 minutes while awake.
8. Further arterial and venous sampling was conducted.

PILOT BLOOD GAS INVESTIGATION RESULTS:

Parameter	Commencement (Before <u>Therahaler</u> <u>THERAHALER</u> ) Average Reading	After 2 hours (Continuous use) Average Reading	After 2 weeks (Every 30 minutes) Average Reading	After 4 weeks (Every 30 minutes) Average Reading
Oxy-haemoglobin	93.69	94.00	94.30	94.75
PO2	92.99	92.09	101.40	91.17
PCO2	39.50	39.80	38.36	39.68
Haemoglobin	15.33	15.61	15.81	15.88

The object of the two tests was to investigate trends to gain a better understanding of how TERAHALER's magnetic field impacts blood physiology. The following findings were made:-

Oxy-haemoglobin: This showed a steady, incremental increase from a starting average of 93.69% to 94.75% four weeks later.

PO2 Levels: The test reveals a slight drop in PO2 levels over the four week period, but the third reading being rather erratic and should be ignored.

PCO2 Levels: Over the four week test, the levels remain almost constant, indicating that improvement in Oxy-haemoglobin levels are not as a result of hyperventilation.

Haemoglobin concentration G/dl: Here, surprisingly, small, but steady incremental increases in haemoglobin concentration from 15.33 to 15.83 were found. Normally, when oxy-haemoglobin levels increase haemoglobin levels decrease.

Conclusion: THERAHALER does improve blood oxygen levels without significantly disturbing blood CO<sub>2</sub> levels.

SURVEY 5: Test for changes in Immunity level function Average Reading

Test Procedure: Seven trialists used the THERAHALER for a four week period and venous blood samples taken initially before THERAHALER usage, after two weeks, after four weeks. CD3, CD4, CD8 levels were noted at these intervals yielding the following results.

RESULTS

Parameter	Commencement (Before Therahaler <u>THERHALER</u> ) Average Reading	After 2 Weeks (Every 30 minutes) Average Reading	After 4 Weeks (Every 30 minutes) Average Reading
CD3	1662,67	1373,5	1724
CD4	982	784	1015
CD8	634	906	675

Conclusion: CD3 and CD4 counts show a significant improvement whilst CD8 shows moderate improvement. When these results are correlated with patient reports from Survey 3 Asthma trials, many patients reported large reductions and in some cases cessation of corticosteroid drug therapy combined with an increase resistance to flu and bronchitis.

SAFETY:

THERAHALER has no reported adverse effects during this test, or any previous tests, and has also proved to be completely compatible with all allotropic medicine regimes

encountered to date. THERAHALER's safety and drug compatibility is one of the device's many outstanding features.